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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,228	11/16/2005	Graham McIntyre	15373.0002	6730
27890	7590	10/03/2006	EXAMINER	
STEPTOE & JOHNSON LLP			SWARTZ, RODNEY P	
1330 CONNECTICUT AVENUE, N.W.			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20036			1645	

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/526,228

Applicant(s)

MCINTYRE ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Preliminary Amendment.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 11-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1March2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/05/7/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Preliminary Amendment is acknowledged.
2. Claims 1-22 are pending. Claims 11-22 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from a multiply depend claim. See MPEP § 608.01(n). Accordingly, claims 11-22 have not been further treated on the merits.
3. Claims 1-10 are under consideration.

Specification

4. The disclosure is objected to because of the following informalities:
 - Page 1, line 30, "urbanisation" should be "urbanization".
 - Page 7, line 10, "to for" should be "for"; line 25, "utilisation" should be "utilization".
 - Page 11, line 31, "utilisation" should be "utilization".
 - Page 13, line 30, "immunising" should be "immunizing".
 - Page 14, lines 1, 18, 20, 27, 31, "immunised" should be "immunized".
 - Page 15, lines 4, 7, 14, 18, 23, "immunised" should be "immunized".
 - Page 19, line 23, "ionising" should be "ionizing".
 - Page 23, line 14, "aerosolised" should be "aerosolized".
 - Page 24, line 5, "paralysed" should be "paralyzed"; line 16, there is no reference in the list on pages 84-85 titled "Kay (2001)".
 - Page 26, line 13, "Health" should be "health".
 - Page 29, line 10, "utilisation" should be "utilization".
 - Page 32, lines 2-3, there is no verb in the sentence; line 13, "hospitalised" should be "hospitalized".

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Page 39, line 21, "optimised" should be "optimized".

Page 40, line 5, "recognised" should be "recognized"; line 9, "recognise" should be "recognize"; line 19, "minimise" should be "minimize".

Page 42, line 7, "release" should be "released"; line 19, "solubilising" should be "solubilizing"; line 21, "stabilisers" should be "stabilizers".

Page 45, line 18, "utilisation" should be "utilization".

Page 46, line 20, "*Tubercule bacilli*" should be "tubercule bacilli".

Page 52, what are the units in Table 1?

Page 55, what are the units in Table 2?

Page 57, what are the units in Table 3?

Page 58, line 21, "immunisation" should be "immunization".

Page 60, line 16, "standardised" should be "standardized".

Page 64, line 25, "immunisation" should be "immunization"; line 30, "*Tubercule bacilli*" should be "tubercule bacilli".

Page 65, line 28, "*Dietza*" should be "*Dietzia*".

Page 66, lines 26 and 28, "immunisations" should be "immunizations".

Page 67, line 3, "*Tubercle bacilli*" should not be in italics.

Page 70, line 11, "weighted" should be "weighed".

Page 71, what is the unit of measure for the data in the table?

Page 73, lines 7, 15, 18, "sweet itch" should be "sweet-itch"; lines 10, 17, "sweetitch" should be "sweet-itch".

Page 75, what is the unit of measure for the data in the tables?

Page 76, line 23, "found in at" should be "found at".

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Page 79, line 18, "was give" should be "was given".

Page 84, the source is missing for references, Sharpe et al, and Manabe et al.

Appropriate correction is required.

Drawings

5. Figure 1 is objected to because labeling of the y-axis appears to be "eight grams" and the title on the figure does not match the title in the Brief Description on page 47.
6. Figure 2 is objected to because the title on the figure is jumbled and does not match the title in the Brief Description on page 47.
7. Figure 3 is objected to because the units of swelling are not identified.
8. Figure 4 is objected to because the units of swelling are not identified and the legend for the graph appears to be TpBCG.
9. Figure 5 is objected to because the units of swelling are not identified and the legend shows a third line with a solid box, but no such line is seen in the graph.
10. Figure 6 is objected to because the units of tuberculin response is not identified.
11. Figure 7 is objected to because the units of swelling are not identified and the legend shows a third line, but no such line is seen in the graph.
12. Figure 8 is objected to because the units of swelling are not identified.
13. Figure 9 is objected to because the units of swelling are not identified.
14. Figure 10 is objected to because the units of swelling are not identified and the y-axis is improperly typed.
15. Figure 11 is objected to because in the title, "Wieight" should be "Weight".
16. Figures 13 to 20 are objected because the quality is too poor to assess any lesions as described in the Brief Descriptions of the figures.

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17. Figure 21 is objected to because there is no explanation of "P", "V" or "T".

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

18. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

19. Claims 4-7 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See

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for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

20. Claims 1-3 and 8-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a composition comprising a whole cell, alive or dead, of a bacterium from the genera *Rhodococcus*, *Gordonia*, *Nocardia*, *Dietzia*, *Tsukamurella*, and *Nocardioides*. The remaining recitation in the claims are merely intended use and therefore place no patentability on the composition. In claims 12 and 14, the composition recites that the composition further comprises "an antigen" or "two or more antigens". The recitation does not restrict the source of the antigen, thus it does not preclude antigens of the claimed bacteria.

Therefore, the claims read on a product of nature, i.e., naturally occurring bacteria, alive or dead.

Claim Rejections - 35 USC § 112

21. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

22. Claims 4-7 provide for the use of a whole bacterial cell, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Matson et al (U.S. Pat. No. 4,599,310).

The claims are drawn to a composition, and a method of making said composition, wherein said composition comprises a whole cell, alive or dead, of a bacterium from the genera *Rhodococcus*, *Gordonia*, *Nocardia*, *Dietzia*, *Tsukamurella*, and *Nocardioides*. The remaining recitation in the claims are merely intended use and therefore place no patentability on the composition.

Matson et al teach compositions comprising a *Nocardioides* sp., strain C49,009, (col. 3, lines 1-55; Table 1; col. 6, line 65 to col. 7, line 39), and teaches the utilization of the bacteria in the manufacture of a medicament for the treatment/prevention of cancer (col. 6, line 65 to col. 8, line 64; Example 1; claims 1-3).

Conclusion

25. No claims are allowed.


26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

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If attempts to reach the Examiner by telephone are unsuccessful, the examiner's acting supervisor, Albert M. Navarro, can be reached on (571)272-0861.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

September 16, 2006